AMENDMENTS TO CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1.-2. (Canceled)

3. (Rejected) A transdermal formulation comprising an adhesive drug matrix reservoir and an effective amount of lasofoxifene or a pharmaceutically acceptable salt thereof.

4. (Rejected) The transdermal formulation of claim 3, wherein the adhesive matrix is a solvent based pressure sensitive adhesive matrix.

5. (Rejected) The transdermal formulation of claim 3, wherein the adhesive matrix is a water based pressure sensitive adhesive matrix.

6.-13. (Canceled)

14. (Previously Presented) A device for administering an active agent to the skin or mucosa of an individual comprising a laminated composite of:

a. a backing layer defining an upper portion of a reservoir and extending to the periphery of a peel seal disk;

b. an active agent-permeable membrane extending to the periphery of the peel seal disk and the backing layer, and underlying the backing layer, the backing layer and membrane defining;

c. the reservoir therebetween that contains a transdermal formulation comprising an effective amount of lasofoxifene or a pharmaceutically acceptable salt thereof;

d. the peel seal disc underlying an active agent-permeable membrane;

e. a heat seal about the periphery of the peel seal disc, the active agent-permeable membrane and the backing layer;

f. an adhesive overlay having a central portion overlying the backing layer and a peripheral portion that extends beyond the periphery of the peel seal disc; and

g. a removable release liner underlying the peripheral portion of the adhesive overlay and the peel seal disc.

15.-16. (Canceled)

17. (Rejected) A method for treating or preventing a disorder associated with estrogen deficiency or disregulation in a subject comprising contacting an application situs of the subject with an effective pharmaceutical formulation of any of claims 3 to 5.

18. (Previously Presented) A method for treating or preventing a disorder associated with estrogen deficiency or disregulation in a subject comprising contacting an application situs of the subject with the device of claim 14.

19. (Previously Presented) A method for treating or preventing a disorder associated with estrogen deficiency in a subject comprising contacting a dermal situs of the subject with the device of claim 14.

20.- 21 (Canceled)

22. (Rejected) The method of claim 17, wherein the pharmaceutical formulation further comprises a drug permeation enhancer.

23. (Rejected) The method of claim 22, wherein the drug permeation enhancer is an effective amount of cell-envelope disordering compound.

24. (Rejected) The method of claim 23, wherein the cell-envelope disordering compound comprises an effective amount of a lower alkanol.

25. (Previously Presented) The device of 14, wherein the pharmaceutical formulation further comprises a drug permeation enhancer.

26. (Previously Presented) The device of claim 25, wherein the drug permeation enhancer is an effective amount of cell-envelope disordering compound.

27. (Previously Presented) The device of claim 26, wherein the cell-envelope disordering compound comprises an effective amount of a lower alkanol.

28. (Rejected) A transdermal device comprising a means for adhering a drug reservoir to the application situs and the transdermal formulation of any of claims 3 to 5.

29. (Rejected) The transdermal device of claim 28, wherein the transdermal formulation further comprises an effective amount of a drug permeation enhancer.

30. (Rejected) The device of claim 29, wherein the drug permeation enhancer is an effective amount of cell-envelope disordering compound.

31. (Rejected) The device of claim 30, wherein the cell-envelope disordering compound comprises an effective amount of a lower alkanol.

32. (Rejected) A method for treating or preventing a disorder associated with estrogen deficiency or disregulation in a subject comprising contacting an application situs of the subject with a transdermal formulation comprising a free form hydroalcoholic gel and an effective amount of lasofoxifene or a pharmaceutically acceptable salt thereof.

33. (Rejected) The method of claim 32, further comprising an effective amount of a drug permeation enhancer.

34. (Rejected) The method of claim 33, wherein the drug permeation enhancer is an effective amount of cell-envelope disordering compound.

35. (Rejected) The method of claim 34, wherein the cell-envelope disordering compound comprises an effective amount of a lower alkanol.

36. (Rejected) A method for treating or preventing a disorder associated with estrogen deficiency or disregulation in a subject comprising contacting an application situs of the subject with a transdermal formulation comprising a liquid reservoir drug formulation comprising an effective amount of lasofoxifene or a pharmaceutically acceptable salt thereof.

37. (Rejected) The method of claim 36, further comprising an effective amount of a drug permeation enhancer.

38. (Rejected) The method of claim 37, wherein the drug permeation enhancer is an effective amount of cell-envelope disordering compound.

39. (Rejected) The method of claim 38, wherein the cell-envelope disordering compound comprises an effective amount of a lower alkanol.

40. (Rejected) The transdermal formulation of claim 3, 4, or 5, wherein the cell-envelope disordering compound comprises an effective amount of a lower alkanol.